K122114

OCT 3 2012

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 16, 2012
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Device: Trade Name:	LOGIQ S7 Expert and LOGIQ S7 Pro Ultrasound System
Common/Usual Name:	LOGIQ S7 Expert and LOGIQ S7 Pro
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K111582 LOGIQ S8 Diagnostic Ultrasound System K092271 LOGIQ E9 Diagnostic Ultrasound System K101874 LOGIQ P6 Diagnostic Ultrasound System K113690 LOGIQ e Diagnostic Ultrasound System K112213 Voluson E6/E8/E8 Expert Diagnostic Ultrasound System
Device Description:	The LOGIQ S7 Expert AND LOGIQ S7 Pro is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 62 cm wide, 86 cm deep and 175 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 7-inch LCD touch screen and color 19-inch LCD image display.
Intended Use:	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology

(including prostate); Transrectal; Transvaginal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Technology: The LOGIQ S7 Expert and LOGIQ S7 Pro employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. LOGIQ S7 Expert and LOGIQ S7 Pro and its applications comply with voluntary standards:

1. IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2,Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ S7 Expert and LOGIQ S7 Pro, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ S7 Expert and LOGIQ S7 Pro to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 3 2012

GE Healthcare
c/o Bryan Behn
9900 Innovation Dr.
Wauwatosa, WI 53226

Re: K122114
Trade Name: LOGIQ S7 Expert
LOGIQ S7 Pro Ultrasound System
Regulation Number: 21 CFR §892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Codes: IYN, IYO, ITX
Dated: July 16, 2012
Received: July 17, 2012

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIQ S7 Expert and LOGIQ S7 Pro, as described in your premarket notification:

Transducer Model Number

C1-5-D	L8-18i-D	11L-D
9L-D	S4-10-D	8C
ML6-15	P2D	3Sp-D
IC5-9-D	P6D	
3CRF-D	RAB4-8-D	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K122114

Device Name: LOGIQ S7 Expert and LOGIQ S7 Pro

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Prescription Use_X___ AND/OR Over-The-Counter Use_NA_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122114

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ S7 Expert and LOGIQ S7 Pro Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N	N	N	N	N	N	N	N	5,6
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	3,5,6
Pediatric	N	N	N	N	N	N	N	N	N	N	3,5,6
Small Organ[2]	N	N	N	N	N	N	N	N	N	N	3,5,6
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	5,6
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	5,6
Cardiac Adult & Pediatric	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	3,5,6
Musculo-skeletal Conventional	N	N	N	N	N	N	N	N	N	N	3,5,6
Musculo-skeletal Superficial	N	N	N	N	N	N	N	N	N	N	3,5,6
Other[4]	N	N	N	N	N	N	N	N	N	N	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	N	N	N	N	N	N	N	N	N	N	3,5,6
Transvaginal	N	N	N	N	N	N	N	N	N	N	3,5,6
Transuretheral											
Intraoperative[8]	N	N	N	N	N	N	N	N	N	N	3,5,6
Intraoperative Neurological	N	N	N	N	N	N	N	N	N	N	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122164

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with C1-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	5,6
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	3,5,6
Pediatric	P	P	P	P	P	P	P	P	P	P	3,5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	3,5,6
Muscülo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	P	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	5,6
Abdominal[1]	P	P	P		P	P	P	P	P	P	3,5,6
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6
Small Organ[2]	P	P	P		P	P	P	P	P	P	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with ML6-15 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6
Small Organ[2]	P	P	P		P	P	P	P	P	P	3,5,6
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	3,5,6
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	3,5,6
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K101874)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 172 CL4

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	5,6
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	P	P	P	P	P	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	3,5,6
Transvaginal	P	P	P		P	P	P	P	P	P	3.5,6
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K12 1147

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with 3CRF-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	5,6
Abdominal[1]	P	P	P		P	P	P	P	P	P	5,6
Pediatric	P	P	P		P	P	P	P	P	P	5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	P	P	P	P	P	5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with L8-18i-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	5,6
Small Organ[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	P	P	P		P	P	P	P	P	P	3,5,6
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with S4-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	5
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	5
Pediatric	P	P	P	P	P	P	P	P	P	P	5
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	5
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	5
Adult Cephalic											
Cardiac Adult & Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 112114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac Adult & Pediatric			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac Adult & Pediatric			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K12114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with RAB4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other[4]	N	N	N		N	N	N	N	N	N	[5,6]
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	P	P	P		P	P	P	P	P	P	[3,5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[3,5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3,5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3,5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3,5,6]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with 8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	P	P	P		P	P	P	P	P	P	5
Pediatric	P	P	P		P	P	P	P	P	P	5
Small Organ[2]	P	P	P		P	P	P	P	P	P	5
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	5
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[3]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K101874)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122114

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ S7 Expert and LOGIQ S7 Pro with 3Sp-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	5,6
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	5,6
Pediatric	P	P	P	P	P	P	P	P	P	P	5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac Adult & Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type. Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K112213)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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